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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/576,620 | 03/08/2007 | Alan P. Kozikowski | GUX-010.01 | 4324 |
| 25181 | 7590 | 08/26/2011 | | |
| FOLEY HOAG, LLP PATENT GROUP, WORLD TRADE CENTER WEST 155 SEAPORT BLVD BOSTON, MA 02110 | | | EXAMINER | |
| | | | CHANG, CELIA C | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1625 | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 08/26/2011 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patent@foleyhoag.com

Office Action Summary**Application No.**

10/576,620

Applicant(s)

KOZIKOWSKI ET AL.

Examiner

CELIA CHANG

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 24-56 and 108-118 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 24-29, 32, 35-51, 54, 108-113 and 116 is/are rejected.
- 7) ☐ Claim(s) 30-31, 33-34, 41-42, 44-45, 52, 55-56, 114-115, 117-118 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Amendment and response filed by applicants dated Jun. 17, 2011 have been entered and considered carefully.

Claims 5-23, 57-107 have been canceled.

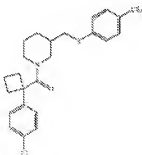
Claims 1-4, 24-56, newly added 108-118 are pending.

2. The rejection of claims 27-29, 32-34, 38-40, 43-45, 49-51, 54-56 under 35 U.S.C. 112 second paragraph for the limitation "halophenyl" or "3-chlorophenyl" for moiety R3 lacking sufficient antecedent basis in the base claim is maintained. Even though applicants can be his/her own lexicographer, the term "aryl" without substitution cannot encompass halophenyl. Please note that the description for aryl did not include substituted phenyl, and the term halophenyl is not "aryl" but a substituted aryl. Nowhere in the specification the concept of a substituted aryl is inclusive in the term aryl and no description of what is this scope.

3. The rejection of claims 1-4, 24-29, 32, 35-40, 43, 46-51, 54, 108-113, 116 under 35 U.S.C. 103(a) as being unpatentable over Aquila et al. US 7,517,892 (cited on 892 dated 7/16/10) is maintained for reason of record.

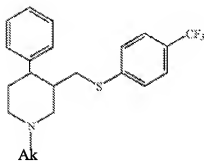
Please note that in the previous office action it was clearly established that US 7,517,892 qualified as a 102(e) date reference because the effective filing date is Sept. 11, 2000 wherein the generic description supported by examples 41-42 were disclosed.

Aquila et al. '892 disclosed examples 41-42 which has the structure:



The exemplified species corresponding to the generic disclosure when R3 is H, R4 is cycloalkyl, R5, R6 forms a CO (see col. 12-13 formula A)

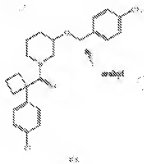
Generically, the R3 moiety is optionally aryl (col. 13, lines 6-7), and R4, R5, R6 can all be H or alkyl (coll. 13, lines 10-15). Therefore, based on the alternative optional of the Markush elements, the above species is tantamount to the compound:



which is the instantly claimed compounds. The picking and choosing of alternative choices among many is prima facie obvious in absence of unexpected results. In re Lemin 141 USPQ 814.

The gist of applicants argument is that the many examples of the Aquila reference does not teach the one methylene insertion between S and the phenyl ring, or the C=O on the 1-piperidine being an alkylene linker.

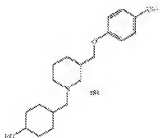
Applicants argued that the generic formula A disclosed on col. 12-13 does not teach any methylene insertion between Z and R1. This is erroneous because it is noted that R1 is phenyl or aralkyl i.e. benzyl. In other words, the methylene was described in the R1 moiety. In addition applicants attention is drawn to col. 103, compound 106 which is



therefore, not only the methylene insertion was generically described but also explicitly exemplified.

Applicants also argued that CR5R6 is C=O which has not been taught to be optionally an alkylene. Please note that the R2 moiety of the instant claims is (CO)R5 which corresponding to

the above compound 41. The instant R2 is also alkyl which includes cycloalkyl (see specification p.6, line 23). Aquila '892, col. 210, compound 188 provided the alternative choice of CR5R6 being alkyl:



The clear teaching in one reference with explicit exemplification and generic guidelines established the prima facie obviousness of the previous office action. Applicants arguments are contrary to the prior art teaching as pointed out in pages and lines of the references. The reason of modifying one proven compound with *attributes* of other proven compounds guided by the generic teaching has been clearly established according to Takeda v Alphapharm recited by applicants.

4. Claims 30-31, 33-34, 41-42, 44-45, 52, 55-56, 114-115, 117-118 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The subject matter wherein R4 is $\text{CON}(\text{R}^6)_2$ is not anticipated nor rendered obvious by the art of record.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Aug. 16, 2011

/Celia Chan,
Primary Examiner
Art Unit 1625